REMARKS/ARGUMENTS

Claims 1, 3-9, 12, 15-19, and 22-25 have been examined. Applicants note with appreciation that these claims are free of any rejections based upon the prior art of record. Claims 11, 13, 37-45, and 47-52 have been cancelled. Claims 26-36 stand withdrawn as being drawn to a non-elected species. Currently, claim 1 is generic with respect to the pending dependent claims. Re-examination and reconsideration of pending claims 1, 3-9, 12, 15-19, and 22-36 are respectfully requested.

Restriction Requirement

Applicants have canceled claims 11, 13, 38-45, and 47-52 without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application.

Amendment to Specification/Drawings

Applicants have added new Figs. 5D and 5E as well as accompanying text in the specification directed at the oblong and elliptical shapes respectively of the catheter body as set forth in originally filed claim 3 pursuant to 37 C.F.R. § 1.83(a) and Examiner's instruction. These amendments are further supported in the originally filed disclosure on page 10, line 33 through page 11, line 2. As such, no new matter has been added.

Applicants have also replaced reference numeral 19 with reference numeral 18 in Fig. 2 to correct an inadvertent clerical error as illustrated in the replacement and annotated sheets.

Rejections Under 35 U.S.C. § 112

Claims 1, 3-9, 12, 15-19, 22-25, and 37 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Claim 37 has been further rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. These rejections with respect to claim 37 are now moot as claim 37 has been canceled. The enablement rejection with respect to claims 1, 3-9, 12, 15-19, and 22-25 is traversed as follows.

Independent claim 1 is directed at an intravascular balloon catheter (10) comprising a catheter body (12) and a first balloon structure (14). The catheter body (12) has a proximal end (16), a distal end (18), a guidewire lumen (20), and an axially slit passage (24) along at least a portion thereof. The first balloon structure (14) comprises a balloon (40), a passage (41) slidably receivable over the catheter body (12), and an inflation tube (26) removably receivable in the axially slit passage (24). This claim is clearly enabled as illustrated in Figs. 2, 4, 5A, and 13A of the originally filed disclosure.

The Examiner contends that:

> [t]he claims(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is it is most nearly connected, to make and/or use the invention. The embodiment of figures 5A, 5B and 13A, as described in the specification and shown in the drawings, is inoperable. The distal end of the inflation tube 26 is shown attached to the back end of inner sleeve 38 in figure 2. Although the inflation tube 26 is slidable within slit 24 since it has a cross-section which is smaller than the cross-section of slit 24, the inner sleeve 38 (which is located relative to the inflation tube 26 as shown in figure 2) will not fit into slit 24. Since the wall of the inner sleeve 38 is located directly in line with the inflation tube 26 as shown in figure 2, the balloon structure 14 is not slidable relative to the catheter body 12 shown in figure 5A, 5B and 13A.

Office Action, pages 3-4. Applicants respectfully disagree. Applicants further note claim 1 requires that the passage (41) of the balloon structure (14) is slidably receivable over the catheter body (12) and that the inflation tube (26) of the balloon structure (14) is removably receivable in the axially slit passage (24). Claim 1 clearly does not require that the inner sleeve (38) be removably received within the axial slit (24). As such, the Examiner's argument falls on this ground.

The Examiner further asserts that:

> If the inner sleeve 38 is located on the outer surface of the catheter body 12, it is unclear what tube or other member connects the inflation tube 26 to the balloon. If there is such a tube, it appears that it must be smaller in diameter than the width of the narrow portion of slit 24 shown at the outer periphery of catheter body 12 shown in figure 13A (since it must pass

> radially outward from inflation tube 26 to the balloon through this portion of slit 24). Yet, no tube or its dimensions are disclosed.

Office Action, page 4.

The test for enablement is whether one reasonably skilled in the art could make the claimed invention from the disclosures in the patent application, when filed, coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01; *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). Although the elected invention of Figs. 5A and 13A show only cross sectional profiles of the embodiment at the midpoint of the catheter body (12) at lines 5-5 of Fig. 2 and lines 13-13 of Fig. 12, it is Applicants position that one of ordinary skill in the art at the time the application was filed could have constructed the claimed balloon catheter of claim 1 based on the patent application disclosure without any undue or unreasonable experimentation.

Several possibilities for the connection between the inflation tube (26) and the balloon (40) could have been implemented at the time of filing without undue experimentation by one of skill in the art, particularly in light of the predictability associated with the mechanical arts. For example, a distal end of the inflation tube (26) may extend out of the axial slit (24), which is of wider width in Fig. 5A, so as to attach to the balloon structure (14). Alternatively, as suggested by the Examiner, another member or tube may be connected at the distal end of the inflation tube (26) so as to allow communication with the balloon (40). The fact that only mid-section illustrations of this claimed embodiment were shown in the drawings of Fig. 5A and 13A, does not render this claim non-enabled. The Examiner is reminded that a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991).

As a *prima facie* case of lack of enablement has not been established by the Examiner, Applicants respectfully request the removal of this 35 U.S.C. § 112, first paragraph rejection, and allowance of independent claim 1 (and dependent claims 3-9, 12, 15-19, and 22-36).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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corrected reference numeral

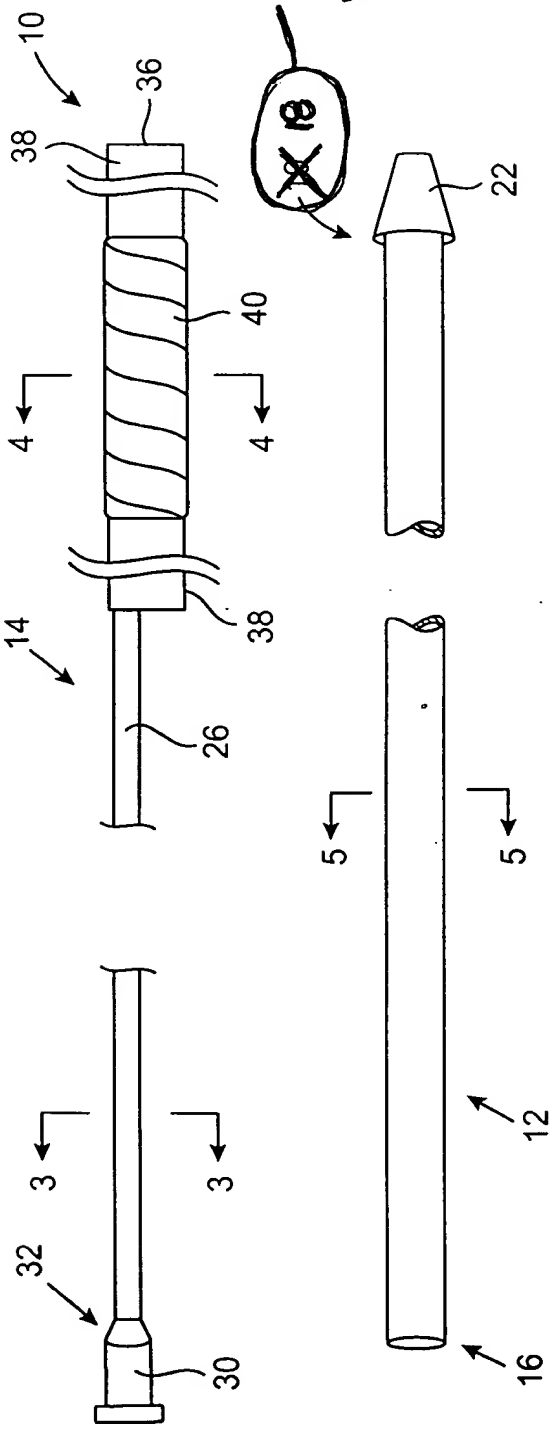

FIG. 2

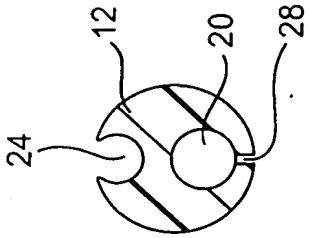

FIG. 5A

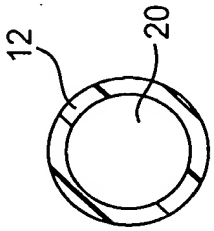

FIG. 5

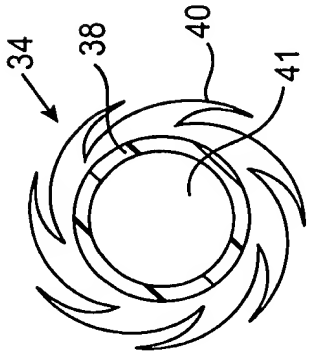

FIG. 4

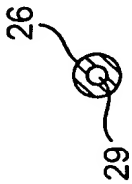

FIG. 3